






**Dorsa Pharmaceutical Company**, Dorsa Pharmaceutical Company, began in 1998, produces two product types: Active Pharmaceutical Ingredients (API) and finished-form pharmaceutical products which has obtained the necessary permits and marketing authorizations and has been fully operational since 2009. The company is a science-led, progressive manufacturer of high quality generic drugs and pharmaceutical formulations, backed by a strong R&D dept. and have recruited some of the best experts in pharmaceutical industry.



 HQ Office: Dorsa Darou Bldg., No. 1 Khajoo St., Salehi Blvd.,  
Jenah Expy., Azadi Sq., Postcode: 1459666876, Tehran, Iran  
Tel: +98 21 546 12000  
 Fax: +98 21 660 08533  
 [www.dorsadarou.com](http://www.dorsadarou.com)  
 [info@dorsadarou.com](mailto:info@dorsadarou.com)  
 [@ export@dorsadarou.com](mailto:export@dorsadarou.com)

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[www.dorsadarou.com](http://www.dorsadarou.com)

**Dorsa Pharmaceutical Co.** as a national awarded science-led company, is the main member of Tavan Pharmaceutical Holding (**TPH**). The uniqueness of this pharmaceutical holding is the complete value chain it can offer to its partners and customers, both nationally and internationally.

**Tavan Institute**, is another strong wing and active member of **TPH** with its highly qualified R&D team and close alliance with university professors, it can support Under-license partnerships by its state-of-the-art analytical and formulatory laboratories. This laboratory has extended experience in preparing the entire regulatory documentation requirements based on Iranian FDA and MOH guidelines. The institute had carried out and compiled more than 40% of all new DMF and CTD files for drug molecules added to the Iranian Drug List (IDL) during the past 10 years. In addition, more than 200 bio-equivalency tests have been established by this laboratory since the beginning of its operation. For this important reason, Iran FDA (IFDA) has awarded this laboratory as one of the few IFDA-Accredited national laboratories, granting it to carry out quality control tests on foods, drugs and cosmetics and has issued GLP certificate to this institute.

**Recpharma Company** (Notarkib Co.) is a TPH Bio-tech member of the group, involved in Human DNA-Recombinant products. **Gamma Interferon** and **Erythropoietin  $\alpha$**  are two main products manufactured in Recpharma with close collaboration by an Austrian Biotech establishment.

With all this support, **Dorsa** aim at organic growth from its own resources with simultaneous openness to partnership and strategic alliances in research and production. Based on our unique position as a research-based drug company, accredited by Vice-Presidency of Science and Technology, and also as a very few holder of cGMP Certificate in Iran (issued based on PIC/S new guidelines) for General Solid Dosage Forms and Ready to Press Granule production line (various forms of Nitroglycerine API) among all other Iranian pharmaceutical companies, we are proud to deliver professional service and products to our partners and customers in and outside the country.

Recognizing the challenges facing health care systems today, we collaborate with regulatory authorities and customers such as health care providers and payers, so that those in need can access our medicines at an affordable price.

**Professional, ethical and compliant, we hold ourselves accountable to deliver value to our customers and shareholders.**

**Quality:** We have learned to provide high quality pharmaceutical products and services, through a decade of persisting to produce high quality finished-form products and purified API bulk (Nitroglycerin API, Nitrodor®). Since quality for us means more than just GMP compliance, we have a comprehensive set of health, safety and environmental policies in place, which has been recognized by national authorities and customers on various occasions.

**Reliability:** Based on our management records, our shareholders and board of director's annual reports, as well as our customer testimonies, they all testify that we are a reliable and loyal long-term partner in this industry.

**Dorsa** is a reliable partner for long-term partnership in Iran pharmaceutical market and strategic business collaborations. We, together, can deliver the right solutions at the right time, building long term relationships with our partners for mutual benefits. While working diligently, we do not give up even when challenged, pursuing innovation in all that we do.

**We are humbled by the opportunity we face to change lives.**

**Sustainability:** We are looking for sustainability by pursuing economy-scale performance, environmental friendly processes and social responsibility campaigns, which can benefit the most for our partners and customers. In simple words, we seek to create value in three dimensions: **People, Planet and Profit**. We are pioneers of eco-friendly technologies and processes for production of Nitroglycerin sustained release granule, which is also observed for our finished-form products proven by several innovations in Green technology.

This has been the base for assessment and awarding Dorsa Pharmaceutical Co. as a National science-led company in 2014.

**We are committed to our employees, for diversity and equal opportunity and environmental sustainability.**

### Production Lines

**Dorsa Pharmaceutical Co.** began in 1998, manufacturing two product types: **API** and **Finished-form pharmaceutical products** and after obtaining the necessary permits and marketing authorizations, it became fully operational in 2009. **Dorsa is interested in expanding cooperation with other international companies around the world.** Our company has the capability of manufacturing different diluted forms of **Nitroglycerin API bulk (Nitrodor®)** for use in different finished dosage forms. **Nitroglycerin API bulk (Nitrodor®)** can be supplied as granules in anhydrous lactose form for tablet pressing or diluted in ethanol for injection products.

## Company Profile



**Nitrodor®** can also be supplied diluted in Miglyol for sub-lingual pearls and inhalation spray. **Nitrodor®** can be used for patch and ointment preparations too.

**Dorsa constantly updates its GMP standards, abiding current guidelines and legislation enforced by Iran FDA and in accordance with PIC/S international standards, to proudly keep its cGMP Certificate valid.**

### Certificates

**Iran FDA (MOH) has become an official member of PIC/S since January 2018.**

Since the start of this membership and stricter standards enforced, very few local manufacturers managed to obtain Iran FDA GMP certificate, and we are proud to be one of them.

#### List of Certificates obtained by Dorsa:

- ✓ GMP: (2018) - Iran FDA Certificate for General Solid Dosage and Suspension Forms issued based on new PIC/S guidelines .
- ✓ cGMP: (2018) - Iran FDA Certificate for Pharmaceutical Raw Material (API) issued based on new PIC/S guidelines.
- ✓ National Customer Care Trophy: (2017)
- ✓ MITEC, ICS Group International: (2015)
- ✓ ISO9001: (2008)
- ✓ OHSAS18001: (2007)
- ✓ ISO14001: (2004)

### Export Agenda

All our listed products in finished-forms as well as Nitroglycerin API bulk (Nitrodor®) are available for Export markets. API of Nitroglycerin (Nitrodor®) in various forms is available for Export according to your finished form requirements.

**We can re-design our product packaging and translate Patient Information Leaflets (PIL) and product brochures according to your regional requirements.**

We are active in Africa, CIS, MENA, ASEAN and Eurasian countries and we aim to reach more countries in these regions and beyond as part of our **Export Expansion 2020 Agenda**

We are prepared to **Out-license** our products under our brand names for your local production facilities, allowing you to take advantage of local manufacturing governmental support. This Out-licensing can start with secondary packaging moved to primary packaging, followed by pre-mix bulk supply in the final phase.

**Dorsa is also a fully integrated, in-house Contract Manufacturing Organization (CMO) and Contract and Development Manufacturing Organization (CDMO), committed to delivering a better experience for our clients.**

We can arrange to manufacture your designated finished-form products on our production lines using our in-house facilities and professional team members. Our production expertise together with collaboration of **Tavan Institute**, enable us to make formulation process and bio-equivalency testing possible, allowing **Dorsa** to provide complete formulation package and testing process of your finished-form drug product, scheduled to be Contract-manufactured or CDMO at our production site, available to all local and global commercial customers.

We are also capable to launch and market your branded medicinal product in Iranian market, either under your brand name as an Under-license deal or as a new brand name defined under Joint-venture cooperation.

#### Target regions for Export market:

- ✓ Europe
- ✓ Africa
- ✓ South America
- ✓ MENA
- ✓ CIS
- ✓ Eurasia
- ✓ ASEAN

## Product Portfolio: Therapeutic Groups and Pharmaceuticals

Category	Generic Name	Trade Name	Dosage Form & Strength
Cardiovascular System	Nitroglycerin	Dorocontin <sup>®</sup>	2.6 & 6.4 mg Extended Release Tablets
	Atorvastatin	Lipi-Cut <sup>®</sup>	20 & 40 mg Tablets
	Losartan	-	25 & 50 mg Tablets
Antibacterial for Systemic Use, Macrolides	Azithromycin	Azithrodor <sup>®</sup>	250 & 500 mg Capsules 100 & 200 mg/5 ml Powder for Oral Suspension
	Clarithromycin	Claridor <sup>®</sup>	250 & 500 mg Coated Tablets 125 & 250 mg/5 ml Powder for Oral Suspension
	Lansoprazole	Lansider	15 & 30 mg Delayed Release Capsules
Drugs for Gastric Acid related disorders	Esomeprazole	Nexive Forte <sup>®</sup>	20 & 40 mg Delayed Release Capsules
	Omeprazole	-	20 mg Delayed Release Capsules
	Pantoprazole	-	20 & 40 mg Delayed Release Capsules
Respiratory System	Montelukast	Asmont <sup>®</sup>	5 mg Chewable Tablets- 10 mg Film-Coated Tablets
	Cetirizine	Rhinizine <sup>®</sup>	10 mg Tablets
Drugs Used in Diabetes	Pioglitazone	Diador <sup>®</sup>	15 & 30 mg Tablets
	Metformin	Glucodor <sup>®</sup>	500 mg Tablets
Sedative Hypnotic	Zolpidem Tartrate	Zolpra <sup>®</sup>	5 & 10 mg Film-Coated Tablets
Nutraceuticals	Folic Acid plus Iodine	Iodofolic <sup>®</sup>	Folic Acid 500 µg/ Iodine 150 µg
	Folic Acid plus Iodine & 15 Vitamins/Minerals	iVita <sup>®</sup>	Folic Acid 600 µg/ Iodine 150 µg, Vit.E - 15 mg, Vit.D - 15 µg, Vit.C - 90 mg, Vit. B1 - 4 mg, Vit.B2 - 3 mg, Vit.B3 - 20 mg, Vit.B6 - 10 mg, Vit.B12 - 6 µg, Biotine - 150 µg, Pantothenic acid - 6 mg, Zinc - 15 mg, Iodine - 150 µg, Copper - 1 mg, Selenium - 55 µg, Magnesium - 100 mg, Iron - 27 mg
NSAIDs	Acetaminophen Ceffeine Ibuprofen	Dorofen <sup>®</sup>	325/40/200 mg Capsules
Erectile Dysfunction	Sildenafil	Vigrodit <sup>®</sup>	5 & 10 mg Tablets
COX II Selective inhibitors	Celecoxib	Doroxib <sup>®</sup>	200 mg Capsules

Pharmaceutical Semi Finished Materials List	
Trade Name	Name of Product
Nitrodor <sup>®</sup>	Diluted Nitroglycerin 10% w/w in Anhydrous Lactose
-	Nitroglycerin granules 1.6%, w/w for E.R Tablets
-	Diluted Nitroglycerin 5% w/w in Ethanol (for Injection)
-	Nitroglycerin granules 5%, w/w in Miglyol
-	Diluted Nitroglycerin 0.35%, w/w in Miglyol (for Sublingual Pearls)
-	Diluted Nitroglycerin 0.4%, w/w in Miglyol (for Inhalation Spray)



**The purest ready to press Nitroglycerin 1.6% granules (Extended Release) in the world**

## Dorocontin® • Cardiovascular System

- Brand Name:** Dorocontin®  
**Generic Name:** Nitroglycerin  
**Dosage Form:** F. C. Tablets  
**Strength:** 20 & 50 mg  
**Packaging:** Single Unit Dose Blister Package  
100 Tablets (10 x 10)  
**Indication:** Angina pectoris, acute & chronic (treatment & prophylaxis)



Single Unit Dose Blisters (Alu-Alu foil)  
Package 100 Tablets (10 x 10)



## Dorocontin® • Cardiovascular System

- Brand Name:** Dorocontin®  
**Generic Name:** Nitroglycerin  
**Dosage Form:** Extended Release Tablets  
**Strength:** 2.6 & 6.4 mg  
**Packaging:** Bottle of 50 Tablets  
**Indication:** Angina pectoris, acute & chronic (treatment & prophylaxis)



## Losartan® • Cardiovascular System

- Brand Name:** -
- Generic Name:** Losartan
- Dosage Form:** F. C. Tablets
- Strength:** 20 & 50 mg
- Packaging:** Single Unit Dose Blister Package  
100 Tablets (10 x 10)
- Indication:** Hypertention (treatment)



## Lipi-Cut® • Cardiovascular System

- Brand Name:** Lipi-Cut®
- Generic Name:** Atorvastatin
- Dosage Form:** F. C. Tablets
- Strength:** 20 & 40 mg
- Packaging:** Single Unit Dose Blister Package  
30 Tablets (3x10)
- Indication:** Hyperlipidemia (treatment)



## Azithrodo<sup>®</sup> Antibacterials for Systemic Use

- Brand Name:** Azithrodo<sup>®</sup>  
**Generic Name:** Azithromycin  
**Dosage Form:** Powder for Oral Suspension  
**Strength:** 100 & 200 mg/5ml  
**Packaging:** Available in 15 & 30 mg bottles  
**Indication:** Bronchitis, Bacterial exacerbations, acute Otitis media, Cervicitis, Urethritis, Chancroid, Mycobacterium avium complex, Pelvic inflammatory, Pharyngitis, Tonsillitis, Pneumonia, Community-acquired and skin and soft tissue infections (treatment)



## Azithrodo<sup>®</sup> Antibacterials for Systemic Use

- Brand Name:** Azithrodo<sup>®</sup>  
**Generic Name:** Azithromycin  
**Dosage Form:** Capsules  
**Strength:** 250 & 500 mg  
**Packaging:** Single Unit Dose Blister Package 6 Capsules (1x6)  
**Indication:** Bronchitis, Bacterial exacerbations, acute Otitis media, Cervicitis, Urethritis, Chancroid, Mycobacterium avium complex, Pelvic inflammatory, Pharyngitis, Tonsillitis, Pneumonia, Community-acquired and skin and soft tissue infections (treatment)



## Claridor® • Antibacterials for Systemic Use (Macrolides)

- Brand Name:** Claridor®  
**Generic Name:** Clarithromycin  
**Dosage Form:** Powder for Oral Suspension  
**Strength:** 125 & 250 mg/5ml  
**Packaging:** Available in 100ml bottles  
**Indication:** Bronchitis, Bacterial exacerbations, acute Otitis media, Cervicitis, Urethritis, Chancroid, Mycobacterium avium complex, Pelvic inflammatory, Pharyngitis, Tonsillitis, Pneumonia, Community-acquired and skin and soft tissue infections (treatment)



## Azithrodro® • Antibacterials for Systemic Use (Macrolides)

- Brand Name:** Claridor®  
**Generic Name:** Clarithromycin  
**Dosage Form:** Tablets  
**Strength:** 250 & 500 mg  
**Packaging:** Single Unit Dose Blister Package 30 Tablets (5×6)  
**Indication:** Bronchitis, Bacterial exacerbations, acute Otitis media, Cervicitis, Urethritis, Chancroid, Mycobacterium avium complex, Pelvic inflammatory, Pharyngitis, Tonsillitis, Pneumonia, Community-acquired and skin and soft tissue infections (treatment)





## Pantoprazole® • Drugs for Gastric Acid Related Disorders

- Brand Name:** -  
**Generic Name:** Pantoprazole  
**Dosage Form:** Capsules  
**Strength:** 20 & 40 mg  
**Packaging:** Single Unit Dose Blister Package 28 Capsules (2×14)  
**Indication:** Gastroesophageal reflux disease [GERD] (treatment & prophylaxis), Duodenal ulcer (treatment), Duodenal ulcer, Helicobacter pylori-associated (treatment), Gastric ulcer (treatment) Zolliger, Ellison Syndrome, NSAID Induced gastric ulcer



## Omeprazole • Gastric Hyper-secretory Disorders

- Brand Name:** -  
**Generic Name:** Omeprazole  
**Dosage Form:** Capsules  
**Strength:** 20mg  
**Packaging:** Bottle of 14 Tablets  
**Indication:** Gastroesophageal reflux disease [GERD] (treatment & prophylaxis), Duodenal ulcer (treatment), Duodenal ulcer, Helicobacter pylori-associated (treatment), Gastric ulcer (treatment), Zolliger, Ellison Syndrome, NSAID Induced gastric ulcer



## Nexive® Forte • Gastric Acid Related Disorders

- Brand Name:** Nexive® Forte  
**Generic Name:** Esomeprazole  
**Dosage Form:** Capsules  
**Strength:** 20 & 40 mg  
**Packaging:** Single Unit Dose Blister Package 30 Capsules (3×10)  
**Indication:** Gastroesophageal reflux disease [GERD] (treatment & prophylaxis), Duodenal ulcer (treatment), Helicobacter pylori-associated, Gastric ulcer (treatment) Zollinger, Ellison Syndrome, NSAID Induced gastric ulcer



## Lansidor® • Gastric Hyper-secretory Disorders

- Brand Name:** Lansidor®  
**Generic Name:** Lansoprazole  
**Dosage Form:** Capsules  
**Strength:** 15 & 30 mg  
**Packaging:** Single Unit Dose Blister Package 30 Capsules (3×10)  
**Indication:** Gastroesophageal reflux disease [GERD] (treatment & prophylaxis), Duodenal ulcer (treatment), Helicobacter pylori-associated, Gastric ulcer (treatment) Zollinger, Ellison Syndrome, NSAID Induced gastric ulcer



**Diador® • Diabetes**

- Brand Name:** Diador®
- Generic Name:** Pioglitazone
- Dosage Form:** Tablets
- Strength:** 15 & 30 mg
- Packaging:** Single Unit Dose Blister Package 30 Tablets (3×10)
- Indication:** Diabetes, type 2 (treatment)



**Glucodor® • Diabetes**

- Brand Name:** Glucodor®
- Generic Name:** Metformin
- Dosage Form:** Tablets
- Strength:** 500 mg
- Packaging:** Single Unit Dose Blister Package 100 Tablets (5×20)
- Indication:** Diabetes, type 2 (treatment)



## Rhinizine® • Respiratory System

- Brand Name:** Rhinizine®  
**Generic Name:** Cetirizine  
**Dosage Form:** Tablets  
**Strength:** 10 mg  
**Packaging:** Single Unit Dose Blister Package 30 Tablets (3×10)  
**Indication:** Seasonal or perennial allergic rhinitis, Chronic urticaria



## Asmont® • Respiratory System

- Brand Name:** Asmont®  
**Generic Name:** Montelukast  
**Dosage Form:** Tablets  
**Strength:** 5 & 10 mg  
**Packaging:** Single Unit Dose Blister Package 30 Tablets (3×10)  
**Indication:** Symptomatic relief of seasonal allergic rhinitis in patients with Asthma, (prophylaxis and treatment) Exercise, Induced Bronchospasm (prophylaxis)



## Dorofen® • NSAIDs

- Brand Name:** Dorofen®  
**Generic Name:** Acetaminophen/Caffeine/Ibuprofen  
**Dosage Form:** Capsules  
**Strength:** 325/40/200 mg  
**Packaging:** Single Unit Dose Blister Package 20 Capsules (2×10)  
**Indication:** Anti-rheumatic, Analgesic, Antipyretic, Anti-dysmenorrheal Acute pain



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## Doroxib® • Cox-II Selective Inhibitor

- Brand Name:** Doroxib®  
**Generic Name:** Celecoxib  
**Dosage Form:** Tablets  
**Strength:** 200 mg  
**Packaging:** Single Unit Dose Blister Package 30 Capsules (3×10)  
**Indication:** Rheumatoid or osteoarthritis (treatment) Acute pain Ankylosing Spondylitis Rheumatoid Arthritis



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## Vigrodit® • Erectile Dysfunction

- Brand Name:** Vigrodit®
- Generic Name:** Sildenafil
- Dosage Form:** Tablets
- Strength:** 50 & 100 mg
- Packaging:** Single Unit Dose Blister Package 4 Tablets (1×4)
- Indication:** Treatment of Erectile dysfunction.



## Zolpra® • Sedative-hypnotic

- Brand Name:** Zolpra®
- Generic Name:** Zolpidem
- Dosage Form:** Tablets
- Strength:** 5 & 10 mg
- Packaging:** Single Unit Dose Blister Package 30 Tablets (3×10)
- Indication:** Insomnia (short-term treatment)



## iVita® • Nutraceutical

- Brand Name:** iVita®  
**Generic Name:** Folic Acid plus Iodine & 15 Vitamins/Minerals  
**Dosage Form:** Tablets  
**Strength:** Folic Acid 600 µg  
Iodine 150 µg plus 15 Vitamins/Minerals  
**Packaging:** Bottle of 30 Tablets  
**Indication:** iVita® is a combination of iodine and folic acid, and 15 other beneficial nutrients needed for all stages of pregnancy and early motherhood. An ideal supplement for preconception, through pregnancy and breastfeeding.



## Iodofolic® • Nutraceutical

- Brand Name:** Iodofolic®  
**Generic Name:** Folic Acid plus Iodine  
**Dosage Form:** Tablets  
**Strength:** Folic Acid 500 µg  
Iodine 150 µg  
**Packaging:** Single Unit Dose Blister Package 100 Tablets (10×10)  
Single Unit Dose Blister Package 30 (3×10) Tablets  
**Indication:** Iodofolic® is a combination of iodine and folic acid, both important for preconception, pregnancy and breastfeeding.



